

What is claimed is

1. A pharmaceutical composition for the solubilisation of a therapeutic agent which is sparingly soluble in water, excluding cyclosporins, in a carrier composition comprising:

- a) c. 10-50% by weight, based on the carrier composition, of a co-surfactant which is substantially pure or which is in the form of a mixture, having a hydrophilic-lipophilic balance of less than 10 (HLB value according to Griffin), selected from the group consisting of polyglycerol fatty acid esters and sorbitan fatty acid esters;
- b) c. 5-40% by weight, based on the carrier composition, of a pharmaceutically acceptable oil which is substantially pure or which is in the form of a mixture, comprising a triglyceride as essential lipophilic component; and
- c) c. 10-50% by weight, based on the carrier composition, of a nonionic surfactant which is substantially pure or which is in the form of a mixture, having a HLB value of more than 10;

and further optional pharmaceutically acceptable excipients.

2. A pharmaceutical composition according to claim 1 for the solubilisation of c. 1-30% by weight, based on the total weight of the carrier composition, of a sparingly soluble therapeutic agent having a solubility in pure water of less than 500 mg/1000 ml.

3. A pharmaceutical composition according to either claim 1 or claim 2 for the solubilisation of a sparingly soluble therapeutic agent selected from the group consisting of rapamycin, tacrolimus, deoxyspergualin, mycophenolate-mofetil, nifedipine, nimodipine, etoposide, and ibuprofen.

4. A pharmaceutical composition according to any one of claims 1-3, wherein component a) consists of a substantially pure polyglycerol fatty acid or of a mixture of different polyglycerol fatty acid esters, and the polyglycerol chain contains up to and including 10 units of glycerol which are esterified with 1-10 acid esters of saturated or unsaturated carboxylic acids having an even number of 8-20 carbon atoms.

5. A pharmaceutical composition according to claim 4, wherein component a) contains as

polyglycerol fatty acid substantially pure polyglyceryl 2-tetrastearate, polyglyceryl 3-monooleate, polyglyceryl 3-stearate, polyglyceryl 6-dioleate, polyglyceryl 6-distearate, polyglyceryl 10-dioleate, polyglyceryl 10-tetraoleate, polyglyceryl 10-decaoleate or polyglyceryl 10-decastearate, or a mixture of these compounds.

6. A pharmaceutical composition according to any one of claims 1 - 3, wherein component a) consists of a substantially pure sorbitan fatty ester, or of a mixture of sorbitan fatty esters, and the sorbitan skeleton is esterified with 1-3 acid radicals of saturated or unsaturated carboxylic acids having an even number of 8-20 carboxylic atoms.

7. A pharmaceutical composition according to claim 6, wherein component a) contains as sorbitan fatty acid ester substantially pure sorbitan monolaurate, sorbitan monopalmitate, sorbitan monostearate, sorbitan tristearate, sorbitan monooleate, sorbitan sesquioleate or sorbitan trioleate, or a mixture of these compounds.

8. A pharmaceutical composition according to any one of claims 1-7, wherein component b) contains as pharmaceutically acceptable oil ground nut oil, sesame oil, sunflower oil, olive oil, corn oil, soybean oil, castor oil, cottonseed oil, rape-seed oil, thistle oil, grape-seed oil, fish oil or neutral oil, and component c) contains a nonionic surfactant with a hydrophilic component consisting of 15-60 units of ethylene oxid.

9. A process for the preparation of a pharmaceutical composition according to claim 1, which comprises mixing components a), b) and c) and further optional pharmaceutically acceptable water-soluble excipients in any order, dispersing in this mixture the therapeutic agent which is sparingly soluble in water and, if desired, processing the dispersion to a suitable dosage form for oral administration.

10. A process according to claim 9, which comprises filling the dispersion into starch or hard or soft gelatin capsules.

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